

Notice of Allowability

Application No.

09/678,357

Applicant(s)

MARDH ET AL.

Examiner

Khatol S. Shahnan-Shah

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 10/24/2006.
2. ☒ The allowed claim(s) is/are 14-15, 20-24, 27-30 and 32 renumbered respectively 1-12.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of the:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|--|--|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date <u>11/22/06 and 11/27</u> . |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____ |


LARRY R. HELMS, PH.D.
SUPERVISORY PATENT EXAMINER

Attachment to Notice of Allowance

1. Applicants' amendment of 10/24/2006 is acknowledged. Claims 18-19 and 25-26 have been canceled. Claims 14, 15, 20, 21, 22, 23, 24, 27, 28, 29, 30, and 32 have been amended.

Status of claims

2. Claims 1-13, 16, 17, 18, 19, 25, 26, 31, and 33-34 have been canceled.
3. Claims 14, 15, 20, 21, 22, 23, 24, 27, 28, 29, 30, and 32 are pending and under consideration.

Objections Moot

4. Objections to claims 18 and 19 made in paragraph 6 of the office action mailed 4/26/2006 is moot in view of cancellation of said claims.

Objections Withdrawn

5. Objection to claim 14 made in paragraph 6 of the office action mailed 4/26/2006 is withdrawn in view of applicants' amendments.

Rejections Moot

6. Rejection of claims 18-19 under 35 112 first paragraph made in paragraph 8 of the office action mailed 4/26/2006 is moot in view of cancellation of said claims.
7. Rejection of claims 18-19 and 25-26 under 35 112 second paragraph made in paragraph 10 of the office action mailed 4/26/2006 is moot in view of cancellation of said claims.

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8. Rejections of claims 18-19 and 25-26 under 35 103 (a) made in paragraphs 12 and 13 of the office action mailed 4/26/2006 is moot in view of cancellation of said claims.

Rejections Withdrawn

9. Rejection of claims 14-15, 20-24, 27-30 and 32 under 35 112 second paragraph made in paragraph 10 of the office action mailed 4/26/2006 is withdrawn in view of applicants' amendments.

10. Rejections of claims 14-15, 20-24, 27-30 and 32 under 35 103 (a) made in paragraphs 12 and 13 of the office action mailed 4/26/2006 is withdrawn in view of applicants' amendments and arguments.

Examiner's Amendment

11. Authorization for this examiner's amendment was given in a telephone interview with Marina T. Larson (reg # 32038) on 11/27/2006.

Please amend claim 21:

21. (currently amended) The method according to claim 14, wherein a concentration of *Helicobacter pylori* antibodies differing from that of the normal population is indicative of antrum gastritis, or pangastritis.

Allowable Subject Matter

12. Claims 14-15, 20-24, 27-30 and 32 are allowed. Claims are renumbered 1-12 respectively.

The following is an examiner's statement of reasons for allowance:

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The claims are drawn to:

A method for diagnosing possible presence of gastritis in a human by evaluating a blood sample, comprising the steps of:

a) assaying the blood sample for the presence of antibodies specific for H, K-ATPases,

b) assaying the blood sample for the presence of antibodies specific for *Helicobacter pylori*,

c) assaying the blood sample for the concentration of pepsinogen I, and

d) comparing the presence of H, K-ATPase antibodies, *Helicobacter pylori* antibodies, and pepsinogen I concentration to the respective values of H, K-ATPase antibodies, *Helicobacter pylori* antibodies, and pepsinogen I concentration of a normal population, and

e) further comprising the steps of multiplying the concentration of pepsinogen I by the concentration of *Helicobacter pylori* antibodies to get a number, and comparing the number to a number calculated similarly for the normal population,

f) wherein concentrations of H, K-ATPase antibodies, *Helicobacter pylori* antibodies, and pepsinogen I in the sample and the number obtained by multiplying the concentration of pepsinogen I by the concentration of *Helicobacter pylori* antibodies that are different from respective corresponding values in the normal population are indicative of gastritis.

The prior art fails to teach the claimed invention.

The closest prior art Lindgren et al. (European Journal of Gastroenterology and Hepatology, vol. 10, No. 7, pp. 583-588, 1998) teach a method for diagnosing gastritis,

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evaluating blood samples for the presence of antibodies for H,K-ATPase , *Helicobacter pylori* and the concentration of pepsinogen A (pepsinogen I) by immunoassay (see abstract). Lindgren et al. teach that the antibodies to H,K-ATPase were determined using an enzyme-linked immunoabsorbent assay, *Helicobacter pylori* antibodies were determined using enzyme immunoassay and pepsinogen I serum level was determined by a double –antibody radioimmunoassay.

However, Lindgren et al. **do not teach the step of multiplying the level of pepsinogen by the level of *Helicobacter pylori* antibodies.**

Lin et al. (Journal of Gastroenterology vol. 30, pp. 156-161, 1995) teach using a scoring system in diagnosis of gastric endocarcinoma using combined assay of serological markers of *Helicobacter pylori*, pepsinogen I and gastrin. Lin et al. teach multiplying value of **pepsinogen I by the level of gastrin** and develop a scoring system for diagnosis. But does not teach **multiplying the concentration of pepsinogen I by the concentration of *Helicobacter pylori* antibodies.**

13. Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled “Comments on Statement of Reasons for Allowance.”

Conclusion

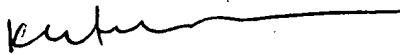
14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Khatol S Shannan-Shah whose telephone number is (571)-272-0863. The examiner can normally be reached on 7:30am-4 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffery Siew can be reached on (571) 272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Khatol Shahnan-Shah, BS, Pharm, MS

Biotechnology Patent Examiner

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November 26, 2006